

## REMARKS

Claims 1-26 have been previously canceled without prejudice to filing a divisional or continuation application. Claims 27-38 are pending.

### **Interview Summary**

The Applicants note with appreciation the courtesy extended to the Applicants' attorney, Philip Yip, in the telephone interview of August 2, 2005. During the interview, the Examiner and Philip Yip discussed the paper copy of an e-mail message that was submitted as evidence with the response filed on December 10, 2004 but was missing in the USPTO file and that the Applicants would submit the e-mail message again.

### **Objection and Rejection**

#### 17 CFR §1.131 Declaration

The Examiner asserted that the 17 CFR §1.131 declaration filed on 12/14/04 did not submit scientific evidence to show that applicant has possession of the process currently claimed and that statements should be supported by evidence that establish the process prior to the invention of the Braun (5662928) reference.

After talking to the Examiner, Applicants' Attorney became aware that for some reason the USPTO case file did not contain the paper copy of the Email message that was submitted by Applicants as evidence supporting the declaration. Thus, Applicants are submitting a paper copy of the same e-mail message again (EXHIBIT A). The e-mail message was sent by a Jim Osborne and forwarded to Scott Bura on July 5, 1994. The email message reported that the melting of scopolamine anhydrous crystals was confirmed by Joan Huey-Dow and discussed annealing. Thus, it clearly established that we melted the crystals, recognized that the crystals as anhydrous scopolamine crystals and had a process of melting and annealing the crystals to eliminate the crystals. Please note the statements: "...deal with the crystal problem the same as before .....heating the laminate above the melting temperature to eliminate the crystal ....annealing .....above the melting temp (69C)." (Emphasis added).

Further, as further support, Applicants also submit herewith a memo (dated September 15, 1994) submitted from J.H. Dow to M. Ekelund containing DSC tracings showing the melting of anhydrous crystals on a punched system and on a laminate (EXHIBIT B). Please note that the DSC tracings were dated Sept 14, 1994. Further, a copy of a page of Scott Bura's notebook showing an annealing experiment done on scopolamine laminate in March 1995 is also submitted herewith (EXHIBIT C).

Thus, the evidence clearly supports that Applicants had possession of the claimed invention prior to the filing date of the Braun patent (5662928).

### 35 USC §102 Rejection

The Examiner rejected claim 27-32 and the newly added claims 33-38 as being the anticipated by Patent No. 5662928 (Braun). As stated above, Applicants submitted, with evidence, a declaration by Scott A. Bura, who is one of the co-inventors of the present application, to antedate said 5662928 Braun patent. Further, the Braun patent is entirely unrelated to anhydrous crystals.

Therefore, the Braun patent is antedated and is removed as a reference. Withdrawal of the rejection is respectfully requested.

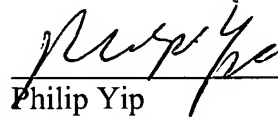
### CONCLUSION

Applicants submit the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC §112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

Applicants hereby authorize the Director to charge Deposit Account 10-0750 for the fees set forth on the accompanying fee transmittal sheet. If it is determined that underpayment or overpayment has been made, the Director is authorized to debit or credit the said deposit account, respectively.

Respectfully submitted,

Dated: August 18, 2005

  
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**CONFIDENTIAL**

**EXHIBIT A**

[33] From: Marc Ekelund at ALZA-V 7/5/94 2:37PM (4142 bytes: 1 ln)  
To: Scott Bura at ALZA-NR, John Dohner at ALZA-M  
Subject: Re[4]: Scop crystal investigation samples

----- Forwarded -----

From: Jim Osborne at ALZA-BCQ 7/5/94 12:44PM (3909 bytes: 1 ln)  
To: Kraig Evans at ALZA-V, Marc Ekelund at ALZA-V  
cc: Joan-Huey Dow at ALZA-NR  
Subject: Re[4]: Scop crystal investigation samples

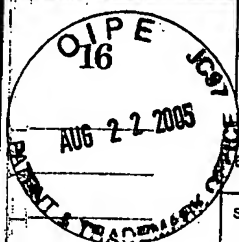
----- Message Contents -----

Joan has confirmed the melting point reported by McCrone (about 69C), by two techniques, microscopy and DSC. Also, samples placed in a humid environment for four days changed slightly in appearance, and the melting point apparently dropped to about 59C after four days hydration, which is consistent with the Scop hydrate crystals we had in systems a few years ago. There will be a few other tests to confirm the identity of the crystals, including consultation with Myron to see if there are analytical techniques that will directly identify, but it appears the crystals in the system are anhydrous Scop crystals. The mystery for me is why are we now getting anhydrous crystals in the system rather than hydrate crystals as before.

We do not see any kinetic limitation to melting the crystals. The crystals melt as soon as they reach the melting temperature and not before. Are you planning to try to deal with this crystal problem the same as before, by heating the laminate above the melting temperature to eliminate the crystal seeds. If so, then the observations on melting kinetics say the annealing time is not important as long as you get the entire laminate above the melting temp (69C). Another way you could consider is to convert the crystals to hydrate form prior to annealing, and then anneal the same as the current annealing protocol. I am not sure how you can practically perform that conversion to hydrate. Jim

Denby Separator

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PROJECT NAME SCOPNOTEBOOK NO 3754

MC 3-15-95

|  |         |   |         |                        |         |               |                    |  |
|--|---------|---|---------|------------------------|---------|---------------|--------------------|--|
| Edition<br>03/12/91                                    |         | OPERATING — SET-UP CONDITIONS FOR<br>FILM COATING/LAMINATION LINE<br>FOR DRUG RESERVOIR |         |                        |         |               | Form No.<br>PF D-2 |  |
| Supersedes<br>07/14/89                                 |         |   |         |                        |         |               | Page(s)<br>1 of 1  |  |
| Code No.<br><u>EXP</u>                                 |         | Control No.<br><u>EXP</u>   |         | Date<br><u>3-15-95</u> |         |               |                    |  |
| Record operating temperature at least twice each shift |         |   |         |                        |         |               |                    |  |
|  | DR      | ANNEALING   | C/A     | ANNEALING              | F/L     | FIL ANNEALING |                    |  |
| Date   | 3-15-95 | 3-15-95   | 3/15/95 | 3/15/95                | 3-15-95 | 3-15-95       |                    |  |
|  | 3-15-95 | 3-15-95   | 3/15/95 | 3/15/95                |         | 3-16-95       |                    |  |
| Time   | 1300    | 1550  | 1850    | 2115                   | 2230    | 2335          |                    |  |
|  | 1445    | 1720  | 1945    | 2145                   |         | 0035          |                    |  |
| Pump Speed (rpm)                                       | 19.7    | N/A   | 39.1    | N/A                    | N/A     | N/A           |                    |  |
|  | 19.7    | N/A   | 39.1    | N/A                    | N/A     | N/A           |                    |  |
| Average Thickness (mil)                                | 2.0     | N/A   | 2.1     | N/A                    | N/A     | N/A           |                    |  |
|  | 1.9     | N/A   | 2.0     | N/A                    | N/A     | N/A           |                    |  |
| Line Speed (fpm)                                       | 2.0     | 2.0   | 3.5     | 3.5                    | 20      | 2.00          |                    |  |
|  | 2.0     | 2.0   | 3.5     | 3.5                    |         | 2.00          |                    |  |
| Dryer Temperature                                      |         |   |         |                        |         |               |                    |  |
| Dryer 1  | 63      | 63  | 63      | 63                     | N/A     | 63            |                    |  |
|  | 63      | 63  | 63      | 63                     |         | 63            |                    |  |
| Dryer 2  | 62      | 62  | 63      | 62                     | N/A     | 62            |                    |  |
|  | 62      | 62  | 63      | 63                     |         | 62            |                    |  |
| Dryer 3  | 92      | 92  | 91      | 90                     | N/A     | 91            |                    |  |
|  | 92      | 92  | 91      | 90                     |         | 90            |                    |  |
| Dryer 4  | 91      | 90  | 91      | 90                     | N/A     | 90            |                    |  |
|  | 91      | 91  | 90      | 90                     |         | 89            |                    |  |
| Dryer 5  | 93      | 92  | 93      | 92                     | N/A     | 91            |                    |  |
|  | 93      | 92  | 92      | 92                     |         | 91            |                    |  |
| Dryer 6  | 78      | 78  | 79      | 77                     | N/A     | 77            |                    |  |
|  | 78      | 78  | 77      | 77                     |         | 77            |                    |  |
| Modpar Tension (lb)                                    | 8.5     | N/A   | 22.5    | N/A                    | 3.5     | N/A           |                    |  |
| Interleaving Tension (lb)                              | 2.5     | N/A   | 3       | N/A                    | 2       | N/A           |                    |  |
|  | 2.6     | N/A   | 3       | N/A                    |         | N/A           |                    |  |
| Take-up Tension (lb)                                   | 7       | 7   | 7       | 7                      | 7       | 7             |                    |  |
|  | 7       | 7   | 7       | 7                      |         | 7             |                    |  |
| Laminating Air Pressure (psi)                          | 38      | N/A   | 38      | N/A                    | 50      | N/A           |                    |  |
|  | 38      | N/A   | 38      | N/A                    |         | N/A           |                    |  |
| Daily Cleaning per SOP 1-034 (Initial)                 | M       | DD  | SE      | RS                     | M.M     | M.M           |                    |  |
|  | PH      | PH  | DD      | RS                     |         | M.M           |                    |  |
| Performed By   | M       | DD  | SE      | RS                     | M.M     | M.M           |                    |  |
|  | PH      | PH  | DD      | RS                     |         | M.M           |                    |  |
| Checked By   | omov    | PH  | PH      | PH                     | RS      | AS            |                    |  |
|  | SR      | SR  | RS      | PH                     |         | APJ           |                    |  |

PRODFORM/PRODFORMD-2, 03/12/91 LES

3/15/95

3/15/95

CELGARD TENSION (lb): 0.9 38 3-15-95 PH 3/15/95

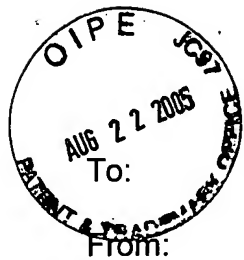
CELGARD TENSION (lb): 0.9 DD 3/15/95 RS 3-15-95

SIGNATURE

DATE 19

READ AND UNDERSTOOD

DATE 3/21/95



**EXHIBIT B**

To: M. Ekelund

From: J.-H. Dow

Date: September 15, 1994

Subject: DSC Scans of Scop Samples with Crystals

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Three Scop samples were tested by DSC to determine the melting point of the crystals.

|                                    |             |
|------------------------------------|-------------|
| Figure 1: Scop TTS from Ciba-Geigy | Mp = 52.5°C |
| Figure 2: Exp Scop, punched system | Mp = 68.6°C |
| Figure 3: Exp Scop, laminate       | Mp = 69.8°C |

As expected, the Scop TTS from Ciba-Geigy has a lower melting temperature than the other two Exp Scop samples. Therefore, the crystals in the former sample should be hydrous Scopolamine as compared to the anhydrous crystals found in the two Exp Scop samples and other Scop samples investigated recently.

These samples will be examined again by hot stage light microscopy to confirm the melting point of the crystals.

Sample: SCOP TTS Ciba-Geigy  
Size: 7.2400 mg  
Method: GENERAL SCAN I (10)  
Comment: RT TO 200°C @ 10°C/MIN, C-P

DSC

File: C:SCOP0.111  
Operator: SCC  
Run Date: 14-Sep-94 10:25

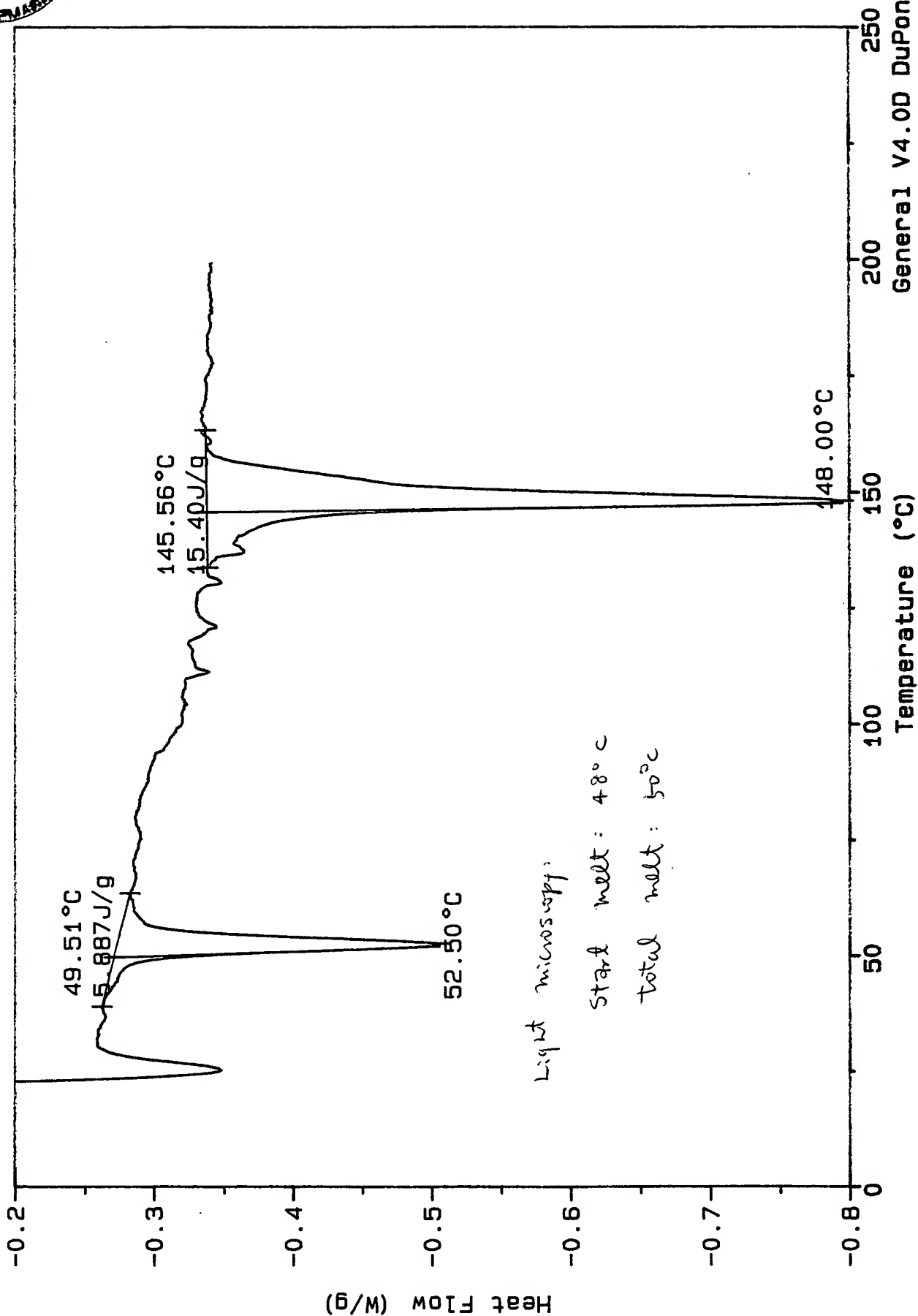


Figure 1

Sample: EXP SCOP Punched system  
Size: 7.2500 mg  
Method: GENERAL SCAN I (10)  
Comment: RT TO 200°C @ 10°C/MIN, C-P

DSC

File: C:SCOP0.113  
Operator: SCC  
Run Date: 14-Sep-94 11:27

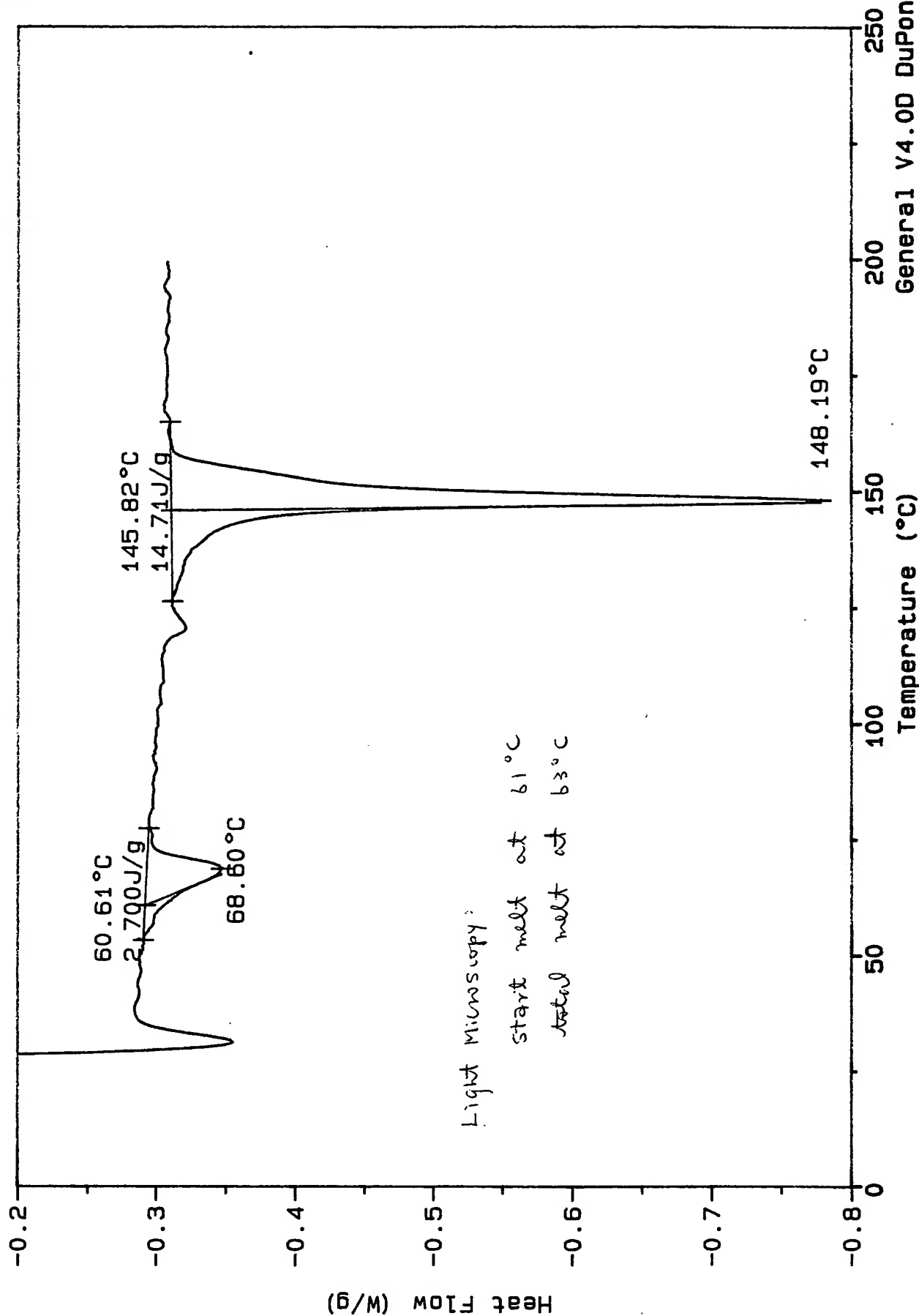


Figure 2





Laminate  
Sample: SCOP SHEET (EXP SCOP)  
Size: 8.7800 mg  
Method: GENERAL SCAN I (10)  
Comment: RT TO 200°C @ 10°C/MIN, C-P

DSC

File: C:SCOP0.112  
Operator: SCC  
Run Date: 14-Sep-94 10:58

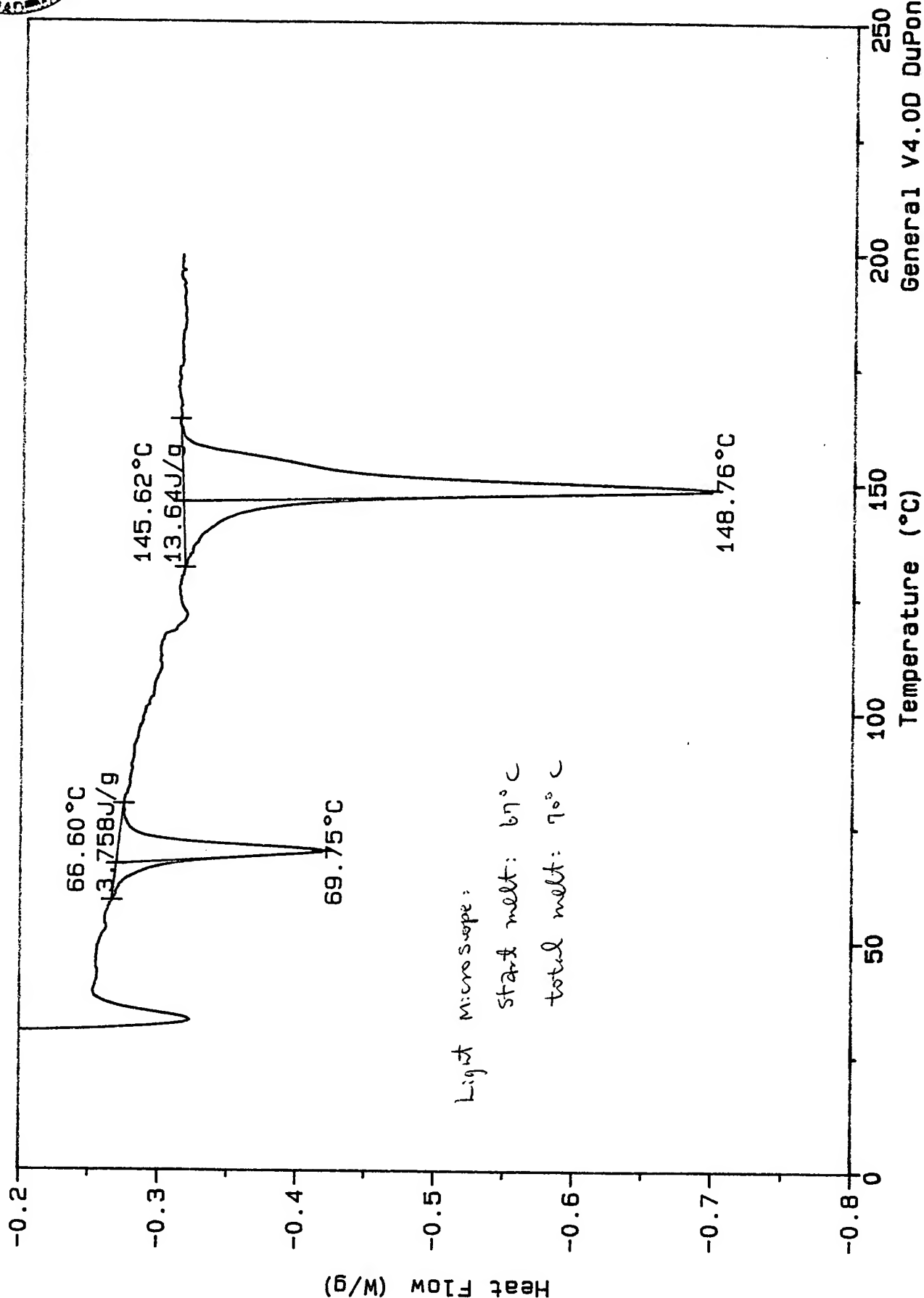


Figure 3